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| APPLICATION NO.   | FILING DATE           | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|---|-----------------------|----------------------|-------------------------|------------------|--|
| 10/723,208 11/26/2003   |                       | Mark R. Hellberg     | 2162 (3010-009-1)       | 8524             |  |
| 33432   | 33432 7590 08/26/2005 |                      |                         | EXAMINER         |  |
| KILYK & BOWERSOX, P.L.L.C. 53 A EAST LEE STREET WARRENTON, VA 20186 |                       |                      | SAEED, KAMAL A          |                  |  |
|   |                       |                      | ART UNIT                | PAPER NUMBER     |  |
|   | •                     |                      | 1626                    |                  |  |
|   |                       |                      | DATE MAILED: 08/26/2005 | 5                |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|  | Application No.  | Applicant(s)                       |  |  |  |  |  |
|--|--|------------------------------------|--|--|--|--|--|
|  | 10/723,208   | HELLBERG ET AL.                    |  |  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit                           |  |  |  |  |  |
|  | Kamal A. Saeed   | 1626                               |  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply |                                    |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                                    |  |  |  |  |  |
| Status   |  |                                    |  |  |  |  |  |
| 1) Responsive to communication(s) filed on   | _•   |                                    |  |  |  |  |  |
|  | ·_ ·   |                                    |  |  |  |  |  |
| 3) Since this application is in condition for allowar  | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                                    |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |  |                                    |  |  |  |  |  |
| Disposition of Claims  |  |                                    |  |  |  |  |  |
| 4) Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) 3-5,8 and 11-14 is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 1,2,7,9 and 10 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.   |  |                                    |  |  |  |  |  |
| Application Papers   |  |                                    |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |  |                                    |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |  |                                    |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |  |                                    |  |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  U.S. Patent and Trademark Office   | 6)  Other:   | te atent Application (PTO-152)     |  |  |  |  |  |
| PTOL-326 (Rev. 1-04) Office Ac   | tion Summary F   | Part of Paper No./Mail Date 082105 |  |  |  |  |  |



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#### **DETAILED ACTION**

Claims 9-14 have been added. Therefore, claims 1-14 are pending in this application. Claims 3, 5, 8 and 11-14 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

## Response to Amendment and Remarks

Applicants amendment and arguments was persuasive to overcome the rejections of claims 1, 2, 7, 9 and 10 as set forth in the Office Action mailed on October 4, 2004. The method of use claims have not being rejoined because the compounds have not been found allowable.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 7, 9 and 10 are rejected under 35 U.S.C. 103 (a) as being obvious by GB 1005024.

Applicants instant elected invention in claims 1 and 2 teach compounds of formula I,

, depicted in claim 1 as defined in claim 1

Determination of the scope and content of the prior art (MPEP §2141.01)

GB 1005024 teach compounds of the Formula

and their pharmaceutical

use.

### Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art of Gold et al, is that R<sub>3</sub> of the Formula depicted in claim 1, of this application is limited to C1-C3 alkyl while the prior art teach hydrogen in that position.

### Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

One skilled in the art would have found the claimed compound prima facie obvious because it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Wood, 199
U.S.P.Q. 137 (C.C.P.A. 1978) and In re Lahr, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The

motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e pharmacological use).

Therefore **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:30 AM- 5:00 PM.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signiture, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive

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data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

KAMAL A. SAEED, PH.D. PRIMARY EXAMINER

Kamal Saeed, Ph.D.,

Patent Examiner, AU 1626